EXHIBIT H

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
MDL No. 1968

IN RE:	VIDEOTAPED
DIGITEK PRODUCT	DEPOSITION OF:
LIABILITY LITIGATION	MARK G. KENNY
	VOLUME I

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TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before CAROL ANN SHEPARD, a Certified Court Reporter of the State of New Jersey, held at the MARRIOTT NEWARK AIRPORT HOTEL, 1 Hotel Road, Newark, New Jersey, on Tuesday, June 29, 2010, commencing at 8:30 in the forenoon.

his question.

Q. It's a very specific question.

Do you have an opinion, to a reasonable degree of probability, as to whether any consumer received a Digitek -- recalled Digitek tablet that was normal in size but outside its USP specifications?

A. Not within a reasonable probability.

Q. All right. Are you a -- do you have any expertise in statistics?

A. I have knowledge of it.

Q. Do you have expertise in it?

A. No. I would not say I'm an expert.

Q. Do you know anything about statistical significance?

A. I have some knowledge of it.

Q. All right. Do you have an opinion as to whether 4 1/2 percent -- let me rephrase that question.

FDA tested 7 of the 152 recalled batches --

A. Okay.

Q. -- independently in these 484s that I have had marked as exhibits.

By my math, that's 4.6 percent.

consumers?

Q. Returned samples from consumers or tests that consumers have of samples that they kept or tests done by the FDA or anybody else to indicate that there are normal-sized tablets outside the specification --

A. I haven't seen any tests.

Q. Okay.

A. So I can't see any tests that are out.

Q. All right. So do you have any evidence at all that Digitek, outside its labeled specifications, reached consumers in this litigation?

A. Please, this is an important question. Repeat it.

MR. MORIARTY: Read that one back, please.

(Requested portion is read.)

A. I have no evidence.

Q. Do you know what a red herring is?

A. I think I do.

Q. Do you know plaintiffs' lawyers in this litigation said, in court and in court documents, that the double-thick theory is a red herring?

MR. MILLER: Object to form.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

BOBBY R. MILLIGAN, et al., Plaintiffs, -vs- ACTAVIS GROUP HF, et al., Defendants.	MDL Case No. 2:09-cv-121 VIDEOTAPED DEPOSITION OF: RUSSELL F. SOMMA, PH.D.

TRANSCRIPT of testimony as taken by and before MARK SCHAFFER, a Certified Shorthand Reporter and Notary Public of the States of New Jersey and New York, at the Marriott Hotel, Newark Liberty International Airport, Newark, New Jersey, on Thursday, July 1, 2010, commencing at 8:31 in the forenoon.

Tape Number 5.

Q. Dr. Somma, I was asking you some questions about your report.

A. Yes, sir.

Q. So let's go to Page 8.

A. Yes, sir.

Q. Now, so far as Batch 70924A is concerned, you are aware that my client, when it finished all of its inspections on that batch, found a total of 20 double-thick tablets. Is that right?

A. That's my understanding, yes, sir.

Q. Okay. Do you have an opinion to a reasonable degree of probability as to whether or not my client, in its inspection of that batch, failed to detect any other extra-thick tablets?

A. In my experience, we never relied on a visual inspection to release a batch.

Q. Sir.

A. I didn't answer the question.

Q. You didn't.

A. No.

MR. MORIARTY: Can you read that question back, please?

Q. It was a very specific question.

(The question is read.)

MR. MILLER: Objection. Asked and answered.

A. Okay. I don't -- the probability is they did not detect all of them.

Q. Do you have an opinion to a probability as to how many were made that were extra thick that were not detected?

A. I don't have a hard and fast rule, but my rule of thumb was if you see 20, you got a thousand. That's just Russ Somma's rule. Opinion, that's all.

Q. And Russ Somma's rule, is it based on controlled trials where you tried visual inspections and tried to see how many were caught or missed?

A. It's based on my experience in scale-up of processing. It has never been confirmed by taking them out and measuring if my rule is correct.

Q. Is it based on peer-reviewed literature?

A. No.

(A discussion is held off the record.)

Q. So it's not based on actual scientific studies where you compared visual inspections' accuracy to actual defect rates?

A. No, Matt, it's not.

Q. So I want to get back to my question.

Do you have an opinion to a probability as to how many extra-thick tablets were made but not caught

A. No, sir.
Q. Okay. So do you see what I'm trying to drive at here? Your level of -- your not being thoroughly convinced that the investigation revealed problems with that one batch does not prove that there was out-of-spec Digitek in the hands of consumers; does it?
MR. MILLER: Object to form.
A. And, again, what I have to point to is that all of the parts have to move and have to work properly. And there's certainly information that says in general, the quality systems here were not functioning properly.
Q. Give me all the affirmative, scientific evidence that you have that any consumers got out-of-specification Digitek in their prescription vials?
A. And, again, if all we rely upon is the specifications, we wouldn't be having this conversation. The answer is: There's got to be another dimension to it, and that dimension is the way in which they manufactured the product, and that is the point I keep trying to make.
I haven't seen anything beyond: They meet specs. If you live by the specs, you die by the

specs. It's as simple as that. That's a narrow-minded approach. And I agree with you, they all met spec.

MR. MORIARTY: I'm going to pass the witness to Ms. Downie.

CROSS EXAMINATION BY MS. DOWNIE:

Q. Dr. Somma, I have just a few questions for you.

You testified earlier today that you were contacted initially by Spyglass, Mr. Kenny's organization. Is that correct?

A. That's correct.

Q. And when were you first contacted by Mr. Kenney?

A. In March.

Q. How many times have you spoken with him regarding this litigation?

A. Two -- three times.

Q. And when he first contacted you, what did he tell you he expected your role to be in this litigation?

A. To be the technical opinion.

Q. And did he provide to you details regarding what the litigation was about?

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL NO. 1968

The videotaped deposition of JAMES J. FARLEY taken by counsel for the Defendants, Actavis Totowa, LLC, Actavis, Inc., and Actavis Elizabeth, LLC, pursuant to notice and by agreement of counsel, reported by Angela S. Garrett, CSR, RPR, B-2407, at the Embassy Suites, 145 Mulberry Boulevard, Savannah, Georgia, on June 28, 2010, commencing at 9:10 a.m.

Q Let's go to the very end of page 19. Okay?

A Yes.

Q And you're talking about since the non-compliance problem was systemic all products, including Digitek, were adulterated as defined in Section 501 of the Food, Drug and Cosmetic Act.

Do you see that?

A Yes.

Q Okay. Is it your understanding that this litigation is about whether Digitek and other products at Actavis were considered adulterated under its regulatory definition?

A That's part of it. It's my understanding that there was a probability that some material produced by Digitek could harm a consumer.

Q Okay. Is there some statement in any FDA document that there is a probability that out-of-specification Digitek was shipped to the marketplace?

A Specifically as you worded that, no.

MR. ERNST: Objection to form.

Q To your knowledge did FDA say anywhere in a 483 or a warning letter that double thick tablets had in fact made it to the marketplace?

A In a 483?

Q Or a warning letter.

A Warning letter? No, they did not say it the way you just worded it.

Q Did the FDA anywhere in a 483 or warning letter say that out-of-specification Digitek tablets had made it to the marketplace or in the hands of consumers?

MR. ERNST: Objection to form.

A I'm pausing because they're not going to say that in a 483. The 483 is going to say what you're doing in the plant, the facility that's being inspected. It's not in the range of a 483 to say whether it's on the marketplace or not.

So that's why I'm looking surprised at the wording of the question, because the answer is not -- it's like, of course, not, it won't in a 483.

Q Okay. Were you aware that FDA in the latter half of 2006 asked Actavis to bring in a consultant for some batch record reviews?

A Yes.

Q And the purpose of that in essence was to see according to the batch record reviews whether products were being made in accordance with GMPs, correct?

A Currently or before?

Q FDA chooses the sample size for their 484 program, don't they?

A Yes.

Q They can take as many samples as they want, couldn't they?

A Yes.

Q So do you have any data anywhere, any scientific data, that shows out-of-specification Digitek in the hands of pharmacists or consumers?

A I don't have scientific data. However, the purpose of a surveillance, also known as survey sample, is to take a sample not indicative of everything that was produced, but a sample to determine if that sample is good or not. It does not tell me that there isn't any harmful Digitek out there. All of this is small.

Q That's nice. What I'm asking you, Mr. Farley, what data do you have that there is in fact harmful out-of-specification Digitek out there in the hands of consumers? Okay? This is what I've got plus more.

A Yes.

Q What have you got?

A If you mean other than the 483s saying it was not made right, you mean analytical data showing

A It sounds to me like you're minimizing the significance of a 483 or a warning letter.

Q No, sir.

A They are serious things.

Q What I'm trying to ask you -- I'm trying to understand your opinions and the support for your opinions.

A Yes.

Q I understand what you relied on, those three categories. I want to know if there's anything else. Okay? You've said warning letters, 483s and a consent decree. Anything else?

A And the double thick tablets that were found and not analyzed, which is surprising.

Q I'm -- maybe you're missing the question.

A I might be.

Q Okay? I want to know any documents that indicate to you the likelihood that out-of-spec Digitek made it to the hands of consumers, okay, hands of consumers, not rejected at the plant.

A Separate from my feeling that there was a good possibility that some might, I haven't seen a document that indicated that there was. But what I'm looking at is not the quantity.

You could show me a hundred more analytical